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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,093	12/01/2003	Fahri Saatcioglu	50218/002004	4578

21559 7590 10/23/2006

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,093	SAATCIOGLU, FAHRI	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The election filed August 7, 2006, is acknowledged and has been entered.

Applicant has elected the invention of Group I, claims 1-13, drawn to a method for detecting a neoplastic cell in a sample, said method comprising determining the amount of a polypeptide comprising the amino acid sequence of SEQ ID NO: 10 in the sample.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The amendment filed August 7, 2006, is acknowledged and has been entered. Claim 14 has been canceled. Claim 1 has been amended.

3. Claims 1-13 are pending in the application and are currently under prosecution.

Priority

4. Applicant's claim under 35 USC § 120 for benefit of the earlier filing date of U.S. Patent Application No. 09/743,683 (now abandoned), filed January 10, 2001, which is the National stage entry of PCT Application No. PCT/IB00/0673, filed May 19, 2000, which claims benefit of U.S. Provisional Application No. 60/135,325, filed May 20, 1999, and U.S. Provisional Application No. 60/135,333, filed May 20, 1999, is acknowledged.

However, claims 1-13 do not properly benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure. Moreover, claims 1-13 do not properly benefit by the earlier filing dates of U.S. Provisional Application Nos. 60/135,325 and 60/135,333, as neither document describes a polypeptide comprising the amino acid sequence of SEQ ID NO: 10.

To receive benefit of the earlier filing date under 35 USC §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Accordingly, the effective filing date of the claims 1-13 is deemed the filing date of the international application, namely December 1, 2003.

Specification

5. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark appearing in the specification is Zeta-Probe™ (see, e.g., page 16, lines 19 and 20).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

> and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims

in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

In this instance, the claims are directed to a method for detecting the presence of neoplastic cells in a sample.

In contrast to the claims, the specification merely describes the overexpression of a gene encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 10 in samples comprising prostate cancer cells.

The specification does not describe with any degree of particularity the overexpression of the gene encoding this polypeptide in samples comprising any type of neoplastic cell, other than prostate cancer. For example, there is no showing that the gene encoding the polypeptide of SEQ ID NO: 10 is differentially expressed in samples comprising breast neoplastic (e.g., cancer) cells.

The skilled artisan cannot predict whether the polypeptide of SEQ ID NO: 10 is differentially expressed in samples comprising other types of neoplastic (e.g., cancer) cells.

The Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than

those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568).

Furthermore, "generalized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). In this instance, there is no language that adequately describes the genus of neoplastic cells that characteristically overexpress the polypeptide of SEQ ID NO: 10, which may be detected in samples according to the claimed process.

With further regard to claim 11, which is directed to a natural or synthetic ligand of the polypeptide of SEQ ID NO: 10, but not necessarily an antibody or antigen binding fragment thereof, there is no language in the specification that adequately describes this genus of ligands that that specifically bind to the polypeptide, which are suitable probes for use in practicing the claimed process. A description of what a material does, rather than of what it is, does not suffice to describe the claimed invention.

The Federal Circuit has decided that a generic statement that defines a genus of substances by *only* their functional activity, i.e., the ability to bind a polypeptide, does not provide an adequate written description of the genus. See *The Reagents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (CAFC 1997). The Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

Although *Lilly* related to claims drawn to genetic material, the statute applies to all types of inventions. "Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to the subject matter unless he can provide a description of the compound sufficient to

distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods". *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1984 (CAFC 2004). Without the ligands to which the claims are directed, it is impossible to practice the claimed invention.

In addition, although the skilled artisan could potentially screen candidate molecules to identify ligands encompassed by the claims, it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Finally, Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of structurally variable ligands, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. In this instance, factual evidence of an actual reduction to practice has not been disclosed by

Applicant in the specification; Applicant has not shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; and Applicant has not described distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention at the time the application was filed.

8. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for using** a method for detecting prostate cancer cells in a sample, said method comprising acquiring a sample of cells and determining whether a polypeptide comprising the amino acid sequence of SEQ ID NO: 10 is present in the sample at an elevated level, as compared to the level of the polypeptide in a control sample comprising non-neoplastic prostate cells, **does not reasonably provide enablement for using** a method for detecting a neoplastic cell in a sample comprising determining the amount of a polypeptide comprising the sequence of SEQ ID NO: 10 in said sample relative to a non-neoplastic control. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

MPEP § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited

to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

As of the filing date sought by Applicant, the amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to have enabled the skilled artisan to use the claimed invention at that time without undue and/or unreasonable experimentation.

The specification merely describes the overexpression of a gene encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 10 in samples comprising prostate cancer cells; the claims, however, are directed to a method for detecting the presence of *any* neoplastic cells in a sample, not necessarily or solely prostate cancer cells. The specification does not describe with any degree of particularity the overexpression of the gene encoding this polypeptide in samples comprising any type of cancer, other than prostate cancer. For example, there is no showing that the gene encoding the polypeptide of SEQ ID NO: 10 is differentially expressed in samples comprising breast cancer cells.

The skilled artisan cannot predict whether the gene encoding the polypeptide of SEQ ID NO: 10 is more abundantly expressed in samples comprising cancer cells, as compared to suitable control samples comprising non-cancer cells; the differential, overexpression of the polypeptide of SEQ ID NO: 10 can only be determined empirically.

This position is supported by the prior art. For example, it is understood that even among closely related protein family members, one cannot reliably and accurately predict whether a particular member of a family of structurally and/or functionally related proteins is associated with the etiology or pathology a specific disease, solely on the basis that one or another member of the family has been shown to have such an association. De Plaen et al. (*Immunogenetics.* 1994; **40**: 360-369), for example,

reviews the structure, chromosomal localization and expression of twelve genes encoding members of the MAGE family of proteins; see entire document (e.g., the abstract). De Plaen et al. teaches six of the members of the gene family were found to be expressed at a high level in a number of tumors of various histological types; while five were very weakly expressed in all samples tested, and one, namely MAGE 7, was not transcribed at all in the ninety-five tumor samples tested (page 367, column 1). Just as not all members of the MAGE family of proteins are associated with cancer, particularly, since is it not obvious what, if any, association the weakly expressed MAGE proteins have, it is apparent that the skilled artisan cannot predict, based upon the information disclosed in the specification, whether the polypeptide of SEQ ID NO: 10 has an association with the etiology or pathology of any given type of cancer (e.g., whether the gene encoding the polypeptide is overexpressed in any other types of cancer other than prostate cancer)[1].

For these reasons, the claimed invention cannot be practiced without first establishing whether the polypeptide of SEQ ID NO: 10 is differentially, overexpressed in samples comprising prostate cancer cells. For this reason, the claimed invention cannot be practiced without undue and/or unreasonable experimentation.

Applicant is reminded reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

In deciding *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (CA FC 1997).

[1] See also Ward (*Developments in Oncology*. 1985; **21**: 91-106).

With further regard to claim 11, which is directed to a natural or synthetic ligand of the polypeptide of SEQ ID NO: 10, which is not necessarily an antibody or antigen binding fragment thereof, the specification fails to describe with any degree of particularity peptides or any other molecules that specifically bind to the polypeptide of SEQ ID NO: 10, which might be used in the construction of probes for use in practicing the claimed process.

One cannot make that which has not been described; and given the lack of a detailed description of ligands of the polypeptide, which are suitable for constructing the probes, it is apparent that the claimed invention could not be practiced without first elaborating upon the disclosure to identify and/or produce such a ligand, and such an elaboration would require the performance of undue and/or unreasonable experimentation.

Thus, the overly broad scope of the claims would merely serve as an invitation to one skilled in the art to identify a ligand having the ability to bind the polypeptide of SEQ ID NO: 10, which might be used as a probe in practicing the claimed invention; yet, defining a substance by its principal biological activity amounts to an alleged conception having no more specificity than that of a wish to know the identity of any material with that biological property. See *Colbert v. Lofdahl*, 21 USPQ2d 1068, 1071 (BPAI 1991).

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, is not deemed sufficient to have enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0137455 A1.

U.S. Patent Application Publication No. 2004/0137455 A1 (Dong et al.) teaches a polypeptide that comprises an amino acid sequence that is identical to the amino acid sequence set forth in the instant application as SEQ ID NO: 10; see entire document (e.g., SEQ ID NO: 2 of the Sequence Listing). Dong et al. teaches the polypeptide is a variant of another polypeptide and is differentially, overexpressed in prostate, ovarian, and endometrial cancer cells, as compared to normal prostate, ovarian and endometrial cells; see, e.g., paragraph [0205]. For example, Dong et al. teaches the variant polypeptide is elevated in endometrial cancer cells by a factor of at least 16-fold; see, e.g., paragraph [0298]. As another example, Dong et al. teaches a 1.5- to 4-fold up-regulation in the level of the protein in ovarian cancer cells; see, e.g., paragraph [0308]. Dong et al. teaches detecting the presence of prostate, ovarian or endometrial cancer cells in a sample by a process comprising determining whether the polypeptide is differentially, overexpressed in samples, as compared to control samples comprising normal cell; see, e.g., paragraph [0205]. Dong et al. teaches the samples are specimens of tissue or biological fluids acquired from patients; see, e.g., paragraphs [0078] and [0091]. Dong et al. teaches the determination is made using an immunoassay employing, as a probe, an antibody or antigen binding fragment thereof

that specifically binds to the polypeptide; see, e.g., paragraphs [0209]-[0225]. Dong et al. teaches the antibody or fragment thereof is detectably labeled with any of a variety of detectable moieties, such as a fluorescent moiety; see, e.g., paragraph [0225].

Conclusion

12. No claim is allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO200277243 A1 teaches the overexpression of a polypeptide comprising the amino acid sequence of SEQ ID NO: 10 in prostate cancer. Korkmaz et al. (*DNA Cell Biol.* 2001 Jul; **20** (7): 435-445) teaches an association between deregulated expression of the polypeptide of SEQ ID NO: 10 and prostate cancer. Stephenson et al. (*J Biol. Chem.* 1999 Aug 13; **274** (33): 23210-23214) teaches the polypeptide of SEQ ID NO: 10 is a prostate-specific antigen. U.S. Patent No. 6,261,562 B1 teaches the polypeptide of SEQ ID NO: 10 is associated with prostate cancer. Japanese Patent No. 2001513886 A teaches the polypeptide of SEQ ID NO: 10 and immunodiagnostics of prostate cancer.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
October 18, 2006